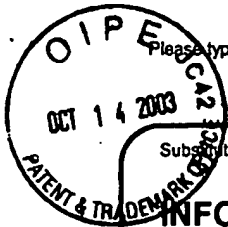


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PTO/SB/08A (10-96)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 5

Complete if Known

Application Number	10/618133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
MB	OO	4,548,716		Boeve	10/22/1985	Entire Patent
MB	PP	4,547,289		Okano et al.	10/15/1985	Entire Patent
MB	QQ	4,495,067		Klein et al.	01/22/1985	Entire Patent
MB	RR	4,381,239		Chibata et al.	04/26/1983	Entire Patent
MB	SS	4,276,177		Smith	06/30/1981	Entire Patent
MB	TT	4,261,834		deWinter	04/14/1981	Entire Patent
MB	UU	4,182,354		Bergstedt	01/08/1980	Entire Patent
MB	VV	4,070,289		Akcasu	01/24/1978	Entire Patent
MB	WW	4,069,153		Gunther	01/17/1978	Entire Patent
MB	XX	3,870,033		Faylor et al.	03/11/1975	Entire Patent
MB	YY	3,860,494		Hickman	01/14/1975	Entire Patent
MB	ZZ	3,648,438		Arbogast	03/14/1972	Entire Patent
MB	AAA	3,601,378		Hurst	08/24/1971	Entire Patent
MB	BBB	3,088,794		Morris et al.	12/18/1962	Entire Patent
MB	CCC	2,362,724		Shea	11/14/1944	Entire Patent
MB	DDD	2001/0050215	A1	Li et al.	12/13/2001	Entire Patent
MB	EEE	2003/0164339	A1	Li et al.	09/04/2003	Entire Patent

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₀
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	FFF	JP	4-114661		Yasushi et al.	04/16/1992	Entire Patent	
	GGG	JP	1-203046		Jun et al.	08/15/1989	Entire Patent	
	HHH	JP	59-112888		Kazuo et al.	06/29/1984	Entire Patent	
	III	JP	67-171403		Atsushi et al.	10/22/1982	Entire Patent	
MB	JJJ	WO	91/04086		Huo et al.	04/04/1991	Entire Patent	

Examiner Signature

M. Severn

Date

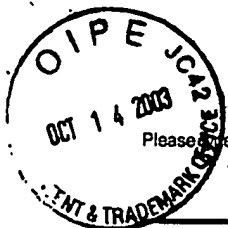
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

Complete if Known

Application Number	10/618,133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
ms	KKK	W. DICKINSON BURROWS and JAMES H. NELSON, IV Fluidmakers: Preparation of Sterile Water for Injection in a Field Setting, Journal of Parenteral Science & Technology, May-June 1993, pp. 124-129, Vol. 47 No. 3	/
ms	LLL	ANDREW W. COLLENTRO, Pharmaceuticals - Practical Microbial Control Techniques for Pharmaceutical Water Purification Systems, Ultrapure Water, March 2002, pp. 53-60	/
ms	MMM	KIYOSHI TSUJI and SUSAN HARRISON, Dry-Heat Destruction of Lipopolysaccharide: Dry-Heat Destruction Kinetics, Appl. Environ. Microb., Nov. 1978, pp. 710-714, Vol. 36 No. 5	/
ms	NNN	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Heat Exchangers to Avoid Contamination, Inspection Technical Guide (ITG) No. 34, July 31, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg34.html (last visited March 29, 1999)	/
ms	OOO	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Pyrogens, Still a Danger, Inspection Technical Guide No. 32, January 12, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg32.html (last visited March 29, 1999)	/
ms	PPP	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), Guide to Inspections of High Purity Water Systems, pp. 1-9, at www.fda.gov/ora/inspect_ref/igs/high.html (last visited March 24, 1999)	/
ms	QQQ	KIYOSHI TSUJI and A.R. LEWIS, Dry-Heat Destruction of Lipopolysaccharide: Mathematical Approach to Process Evaluation, Appl. Environ. Microb., Nov. 1978, pp. 715-719, Vol. 36 No. 5	/
ms	RRR	HANS TRAEGER, Pharmaceuticals - The Presence of Bacteria, Endotoxins, and Biofilms in Pharmaceutical Water, Ultrapure Water, March 2003, pp. 17-22	/
ms	SSS	ALEX KONOPKA, Pharmaceuticals - Current Issues and System Design Considerations Affecting Pharmaceutical Water Systems, Ultrapure Water, March 2002, pp. 22-30	/
ms	TTT	DAVID H. PAUL, Back to Basics - The Combining of Reverse Osmosis and Ion Exchange, Ultrapure Water, July/August 2002, pp. 38-40	/
ms	UUU	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Bacterial Endotoxins/Pyrogens, Inspection Technical Guide (ITG) No. 40, March 20, 1985, pp. 1-10, at www.fda.gov/ora/inspect_ref/itg40.html (last visited March 24, 1999)	/

Examiner
Signature

M. Sweeney

Date

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/618,133
		Filing Date	07/11/2003
		First Named Inventor	Lixiong Li
		Group Art Unit	
Examiner Name			
Sheet 5 of 5	Attorney Docket Number	ARA-US-P1	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
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ms	vv	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Water for Pharmaceutical Use, Inspection Technical Guide (ITG) No. 46, December 31, 1986, pp. 1-4, at www.fda.gov/ora/inspect_ref/itg/itg46.html (last visited October 9, 2003)	/
ms	www	EUROPEAN PATENT OFFICE Abstract - Pyrogen Adsorbent and Removal of Pyrogen Using the Same, JP 4-114661, April 15, 1992	/
ms	xxx	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Resin Carrier, JP 1-203046, August 15, 1989	/
ms	yy	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Aqueous Solution, JP 59-112888, June 29, 1984	/
ms	zzz	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen in Water, JP 57- 171403, October 22, 1982	/

Examiner Signature	m. Savary	Date Considered	7-31-05
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